

*United States Mission
to the
European Union*



How to Export Seafood To the European Union



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I- Introduction

A) Scope of the report:

Given the complexity of the E.U. legislation, this report provides an overview of key E.U. Legislation governing trade in edible seafood products. It does not intend to answer all questions; any additional comments or concerns should be addressed to competent authorities (see Points of Contacts).

B) Background:

Twenty-five countries compose the European Union (E.U.). The current Member States are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the United Kingdom, Latvia, Lithuania, Estonia, Poland, Malta, Cyprus, Hungary, Slovenia, Slovakia and the Czech Republic. The E.U. population is approximately 455 million people. Bulgaria and Romania will not join the EU before 2007. The decision to integrate Turkey is still in discussion.

C) The Institutions:

The E.U. has six different institutions that function in many ways as the different branches of the U.S. government. Among these institutions are the European Commission, the Council of Ministers, the European Parliament and the European Court of Justice.

- The European Commission is the E.U. executive body. It has three main tasks: to initiate E.U. policies, to act as the guardian of E.U. treaties (Rome, Maastricht and Amsterdam), and to supervise implementation of E.U. law. The Commission is divided in 25 directorates general (DG), of which DG Fisheries looks after the fish sector, DG Agriculture and DG Sanco for food safety consumer policy and public health protection. A college of 25 Commissioners, named by their national governments but supposedly independent, heads the Mission.
- The Council of Ministers is made up of government representatives from the 25 Member States. Each Member State is in his turn president of the Council for six months. The Ministers represent their individual country, and so defend their national interests. They are responsible for determining E.U. policies and to vote legislation. The Council has working parties and permanent or special committees consisting of representatives from Member States. The best known is the Committee of Permanent Representatives of the Member States, the COREPER.
- The European Parliament gained power over time. From an advisory-only body, it can now veto legislation in certain areas such as consumer protection, health, environment or the single market. Most of EU Legislation is now adopted according to the co-decision procedure of which the European Parliament is one of the two pillars. It has 732 members, elected for five years.

- The European Court of Justice rules on disputes involving interpretation and application of the E.U. treaties and legislation.

D) European Legislative process:

All EU decisions regarding fisheries involve a consultation procedure. In this procedure, the legislative work is shared between the Commission and the Council: the Commission, which has the power of initiative, submits proposals and the Council makes the final decision. These proposals are initially discussed within the Permanent Representative Committee (COREPER). Before any decision is adopted by the Council, various stages must be completed which, depending on the field concerned, also involve the European Parliament, the Committee of the Regions and the Economic and Social Committee in addition to the Commission and the Council. For food safety related matters, the co-decision procedure is required. This procedure usually takes longer than the consultation procedure.

The Treaty of Amsterdam designed the co-decision procedure to create “equality of arms” between the Council and the Parliament. The Council can adopt no decision without reaching a compromise with the Parliament. Given the complexity of the co-decision procedure, the most important thing to notice at that stage of the report is that it usually takes more than a year between the first reading of the Commission’s proposal and its final adoption by the Council.

E) What are the different types of measures?

Regulations:

A Regulation is a law that is binding and directly applicable in all Member States without any implementing national legislation. Both the Council and the Commission can adopt regulations.

Example: Council Regulation (EC) No 1093/94 of 6 May 1994 setting the terms under which fishing vessels of a third country may land directly and market their catches at Community ports.

Directives:

A Directive is a law binding on the Member States as to the result to be achieved, but the choice of method is their own. In practice, national implementing legislation in form deemed appropriate in each Member State is necessary in most cases.

This is an important point, as businesses affected by a directive have to take account of the national implementing legislation as well as the directive. All directives set a date by which Member States have to transpose it in national legislation. After that date, in case of non-implementation, the directive should remain the basis in case of dispute. The Commission can act against Member States that have not implemented the directive in time.

Example: Council Directive 91/493 laying down the health conditions for the production and the placing on the market of fishery products.

Decisions:

A Decision is binding entirely on those to whom it is addressed. No national implementing legislation is required. Both the Council and the Commission can adopt decisions. Since 1995, the European Parliament can be associated to the adoption process on a limited number of issues.

Example: Commission Decision 95/328 laying down certain transitional measures concerning the certification of fishery products from third countries in order to facilitate the switchover to the arrangements laid down in Council Directive 91/493/EEC.

Recommendations:

A Recommendation has no binding effect (it is not a law). Both the Council and the Commission can adopt recommendations.

Example: Commission Recommendation 92/540 concerning a coordinated program for the official control of foodstuffs for 1993.

F) Who is responsible for what?

The European Commission is now composed of 25 Directorates General (DG).

DG Fisheries & Maritime Affairs handles negotiations of International fishing agreements, resources management, aquaculture, fleet management, and makes the Common Fishery Policy (CFP). It also makes proposals for tariff reduction, tariff suspensions and import quotas. It act as aid to DG Trade, part of which is the E.U. equivalent to the Office of the U.S. Trade Representative) for WTO matters.

Some species are subject to trade restrictions under the Convention on International Trade of Endangered Species, which is covered by DG Environment. So DG Fisheries and DG Environment are working closer and closer due to the current status of worldwide fish resources.

But fishery products are also subject to measures taken by DG Agriculture and DG Internal Market, and to the supervision of DG Health & Consumer Protection (SANCO). DG Agriculture handles the Common Agricultural Policy (CAP) and all “vertical” measures on raw material. They make proposals on all E.U. measures concerning sanitary legislation and inspection, by type of products (beef, pork, poultry, vegetables, seafood, etc).

DG Internal Market deals with “horizontal” measures for processed products. They make legislation on additives, colorings, antibiotics, and labeling. All those texts refer to “foodstuffs”.

DG SANCO is in charge of all scientific committees that advise DG Internal Market and DG Agriculture on matters concerning consumer health. DG SANCO includes also the Food and Veterinary Office (FVO based in Dublin, Ireland). The FVO principal missions are to monitor the observance of food hygiene, veterinary and plant health legislation within the European Union, and to contribute towards the maintenance of confidence in the safety of foods offered to European consumers. The FVO is responsible for auditing Member States’ competent authorities, and to inspect third countries for compliance and/or equivalency to E.U. legislation.

A European Food Safety Authority (EFSA) has been formally created on January 28, 2002. After months of procedures this new European Agency is now effective.

EFSA will cover risk assessment as well as risk communication. The responsibility of risk management a decision-making remains into EU’s Political Institutions’ hands.

Two main sets of legislation greatly influence U.S. seafood exports to the EU: the Common Fisheries Policy (CFP) and the Food Hygiene Legislation.

The CFP establishes a legal framework for the regulation of fisheries and aquaculture activities. It has a direct impact on the EU's production capacity through fleet and quotas management. Therefore it can directly influence imports of seafood from third countries such as the U.S. The Food Hygiene Legislation is the EU's instrument that guarantees safe food to European consumers. It makes sure that "domestically made" as well as imported food complies with minimum EU's hygiene standards.

II- The Common Fisheries Policy (CFP)

A) Overview:

Fishing and aquaculture are important economic activities in the European Union, even if their contribution to the Gross National Product of Member States generally represents less than one percent. However, those sectors can provide more than 10 percent of all jobs in certain zones, such as the Atlantic coast of Spain or Scotland.

With a production of approximately 7.4 million tons of fish (including catches for the fish meal industry), the E.U. is the world's largest fishing power after China and Peru. However being one of the largest markets, the E.U. has a trade deficit of some 3.5 million tons of seafood products, worth about USD 11 billion.

The Common Fisheries Policy (CFP) is the EU's instrument for the management of fisheries and aquaculture. Justification for the Community's involvement in fisheries is perfectly clear being based on Articles 38 and 39 of the Treaty of Rome signed in 1957. It means there must be common rules adopted at Community level and implemented in all Member States, covering all aspects of the fishing industry from the sea to the consumer.

It was only in 1970 that the first common measures were taken. Rules were set for access to fishing grounds, for a common market and for a structural policy to coordinate the modernization of fishing vessels, port infrastructures and processing plants. It was agreed that, in principle, all fishers should have equal access to all waters under the Community jurisdiction. However, a coastal band was reserved for local fishers and those who traditionally fished those areas.

In 1976, Member States followed the worldwide movement to extend their rights from 12 to 200 miles. The change in the international access to fishing grounds really gave impetus to build the actual CFP, born after difficult negotiations in 1983.

The CFP deals with the biological, social and economic dimensions of fisheries. To integrate those multiple areas, it relies on five instruments:

- The policy and conservation management of resources (allocations of Total Allowable Catches and quotas, restructuration plans, technical measures on fishing gears...).
- The structural policy for fisheries (modernization of the fleet, adaptation of activity vis a vis depletion of resources).
- The Common Organization of the Markets (prices of withdrawal, distinction between fishery products and aquaculture products, quality strategies...).
- The International relations (participation of the EU in several international and regional conventions, fisheries agreement with third countries).

- The monitoring and inspection policy (of growing importance within the CFP framework).

The Agenda 2000 has introduced new guidelines for a better CFP, where concepts such as “responsible fishing” and “sustainable development” have been constantly reminded.

In March 2001, the Commission published a “Green Paper” intending to reform the CFP. The overall objective of this future Common Fishery Policy would be to reduce the European fleet and developing its aquaculture industry while paying more attention to environmental and consumer protection.

The first decisions on the reform of the Common Fisheries Policy were adopted by the Council of Ministers on December 2002.

This first legislative package concentrates on four dimensions:

- A multi-annual approach to TACs and quotas
- A new fleet policy
- The control of fishing activities
- A new governance

In October 2005, the European Commission tabled a three-year action program to simplify EU legislation. An [Action Plan for simplifying the Common Fisheries Policy](#) over the period 2006-2008 is the first sectoral action plan adopted in this context. It identifies a series of priority initiatives in two main areas, i.e. conservation and control. The regulations that will be targeted include instruments dealing with quotas and fishing effort, technical measures for the protection of young fish, collection and management of data, monitoring measures, reporting obligations and authorizations to fish outside EU waters. By focusing on conservation and control, the Commission hopes to improve working conditions for both fishermen and public officials in the fisheries sector.

B) The Common Organization of the Market in Fishery and Aquaculture Products:

The Common Organization of the Market in Fishery and Aquaculture Products was first introduced in 1970, and then reviewed in 1993 and amended in 2000 ([Council Regulation 104/2000 of 17 December 1999](#)). Its purpose is to stabilize the market, to guarantee a steady supply of quality products and to ensure reasonable prices for consumers and support fishermen’s incomes.

The five components of the Common Organization of the Markets are:

- Marketing standards and consumer information for fresh products for quality, grades, packaging and labeling for domestic production as well as for imports.
- Producers’ organizations (associations to which fishermen belong on a voluntary basis), officially recognized, they are set up to help stabilize markets fluctuations. Their role is to protect fishermen from sudden changes by adjusting supply to demand. They also help to improve product quality, and to make sure that fishing quotas are respected.
- Interbranch Organizations and Agreements aiming at facilitating a total integration of the sector (from the producer to the consumer).
- Prices and Intervention by which certain species cannot be sold below a given price. Financial support is available to producers’ organizations to withdraw fish from the market

when products reach the floor price. They can be stored to be sold when market improves, or they can be processed.

- Trade with third countries in order to insure an adequate supply to the Community market of raw material intended for the processing industry (tariffs, customs duties, autonomous quotas).

III- The food Hygiene Legislation:

Since January 1, 2006, the EU has a new and updated food & feed legislation.

The so-called “Hygiene Package”, the regulation on microbiological criteria for foodstuffs, the regulation on official food & feed controls and the feed hygiene regulation constitute a complementary set of rules that tighten and harmonize EU food safety framework.

If this Hygiene Package tends to simplify previous complex legislation, it also introduces the concept of “responsibility” of all food and feed operators throughout the entire food chain: “from farm to fork”. This report intends to summarize this new legislation with specific indication regarding fishery products and bivalve mollusks. Although the new food and feed regime does not change substantially the existing requirements on seafood products, there are clarifications that are of fundamental importance while exporting to the EU.

A) Food Hygiene:

The Hygiene Package sets clearer and stricter rules on the hygiene of foodstuffs, specific hygiene rules for food of animal origin, and specific rules for controls on products of animal origin intended for human consumption. While general rules are laid down for all food, specific measures are targeting fishery products and bivalve mollusks.

Under this updated legislation, imported products will be required to meet the same standards as EU goods.

The Hygiene Package is divided into 5 Regulations and Directives instead of 17 previously:

Hygiene 1: [European Parliament and Council Regulation 852/2004](#) on the hygiene of foodstuffs. It includes general and technical requirements for primary production, including HACCP.

Hygiene 2: [European Parliament and Council Regulation 853/2004](#) lays down specific hygiene rules for food of animal origin.

Specifically, Annex I (definition), and Annex III Section VII & VIII (bivalve mollusks and fishery products).

Hygiene 3: [European Parliament and Council Regulation 854/2004](#) lays down specific rules for the organization of official controls on products of animal origin intended for human consumption. Specifically, Chapter III, Annexes II, III and VI.

Hygiene 4: [Council Directive 2002/99/EC](#) lays down health rules governing the production, processing, distribution and importation of products of animal origin.

Annex IV of this Directive has been amended by Annex VI of Regulation 854/2004 (mentioned above).

Hygiene 5: [Council directive 2004/41/EC](#) repeals 17 existing Directives.

Exporters are urged to pay specific attention to Article 4, point 3, paragraph (a) that provides continuation of some existing legislation that are based on Directives 91/492 and 91/493. It is the case for the certification of live bivalve mollusks (96/333/EC)

B) Subsequent Regulations:

In addition to this minimum Hygiene Package, Member States have adopted additional measure that cover more detailed aspects.

Microbiological Criteria for Foodstuffs.

These criteria are fundamental for a coherent food hygiene framework. [Commission Regulation 2073/2005](#) introduces new criteria for certain important food borne bacteria, their toxins and metabolites (such as salmonella, histamine and listeria). These criteria are applicable to products placed on the market during their entire shelf life. In addition, the Regulation sets down certain process hygiene criteria to indicate the correct functioning of the production process.

Implementation measures.

Implementing rules concerning this Hygiene Package ([Commission Regulation 2074/2005](#)) include certificates for certain products, testing methods for marine biotoxins...

Until December 31, 2009 the EU allows transitional arrangements to facilitate the transition phase between old and new food hygiene legislation. The transitional measures are laid down in [Commission Regulation 2076/2005](#).

Implications for third countries exporting to the EU:

The Commission has developed a [Guidance Document](#) addressing the key questions related to EU imports requirements. Food business operators will find all necessary information they need as to the consequences of this new regime on their activity.

C) Feed Hygiene:

Contaminated feed has been responsible for many food crises. [Council Regulation 1831/2003](#) aims at ensuring the safety of feed at all stages, including primary production.

The new legislation introduces compulsory registration of feed operators by their competent authority, while feed businesses dealing with more sensitive substances continue to require approval.

This new Regulation became applicable on January 1, 2006. However, in the absence of specific implementing rules concerning third countries, the existing rules on EU imports continue to apply.

[Questions & Answers on Feed Hygiene.](#)

D) Food and Feed Controls:

The Food and Feed Regulation on official controls - [Council Regulation 882/2004](#) - sets out harmonized EU controls systems, covering both food and feed safety, and animal health and welfare standards. Concerning import controls, third countries will have to guarantee that products intended for the EU market meet the necessary standards. This section does not include animal welfare controls except when there are explicit animal welfare provisions in specific bilateral agreements, which is not the case for the U.S.

[Questions & Answers on Food and Feed Controls.](#)

IV Fishery Products:

A) General provisions:

[EC Directive 91/493/EEC](#) is the main text for fish and fishery products. It concerns both domestic (E.U.) and third countries (non-E.U.) production. It defines EC standards for handling, processing, storing and transporting fish.

It must be noted that processed bivalve mollusks (as well as tunicates, marine gastropods and echinoderms) are subject to both Directive 91/492 and Directive 91/493.

Directive 91/493 lays down rules on conditions applicable to factory vessels, to on-shore plants, to packaging, to storage and transport. Provisions, that may require more details, are set concerning own-checks, parasites (all visible parasites must be removed), organoleptic, chemical and microbiological checks.

Exporters will now refer to the new Food Hygiene Legislation (described above) for the provisions just mentioned.

Other texts must be considered as complements to Directive 91/493 and 91/492:

- Directive 92/48 concerning minimum hygiene rules on board fishing vessels;
- Decision 94/356 to implement an own-check system (HACCP);
- Decision 93/140 concerning parasites (visual inspection, non-destructive method);
- Decision 93/351 concerning the maximum level of mercury;
- Directive 95/71/EC modifying the annex of the Directive 91/493;
- Decision 95/149 fixing TVB-N level for certain species;
- Decision 93/51 fixing microbiological criteria for cooked crustaceans and mollusks;
- Regulation 2001/466/EC setting maximum levels for certain contaminants in foodstuffs, last amended by Commission Regulations 2001/2375/EC and 2002/221/EC;
- Directive 2001/22/EC laying down the sampling methods and the methods of analyzing for the official control of the level of lead, cadmium, mercury and 3-MCPD in foodstuffs;
- Directive 2001/13/EC on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs;
- Decision 2001/183/EC laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532.

- Commission Decision 2002/225/EC laying down detailed rules for the implementation of Council Directive 91/492/CEE as regards the maximum level and the methods of analysis of certain marine biotoxins in bivalve mollusks, echinoderms, tunicates and marine gastropods.
- Commission Decision 2002/226/EC establishing special health checks for the harvesting and processing of certain bivalve mollusks with a level of Amnesic Shellfish Poison (ASP) exceeding the limits laid down by Council Directive 91/492/CEE.
- Commission Regulation 2001/2065/EC laying down detailed rules for the application of Council Regulation 104/2000/EC as regards informing consumers about fishery and aquaculture products.

All EU Regulations regarding seafood can be found on the following website:

http://europa.eu.int/comm/food/fs/inspections/special_topics/guide_thirdcountries_en.pdf

B) Imports:

- **Harmonized versus Non-Harmonized countries:**

Third (non-E.U.) countries authorized to export fishery products to the EU are classified into two categories under [Commission Decision 2006/200/EC](#).

Countries included in List 1 (+ Norway and Iceland as members of the European Economic Area) are “harmonized” or “approved” countries. It means that their legislation requirements are at least equivalent to those governing the E.U. domestic production, and that an E.U. inspection team has audited the competent authority, which satisfied E.U. requirements. A specific decision has been adopted for each of those countries fixing specific import conditions, including the official recognition of the competent authority, a specific model of health certificate and a list of approved establishments.

List 2 includes third countries that have given, at least on paper, enough guarantees concerning their inspection system and their legal sanitary requirements. But an E.U. team of inspectors has not yet visited those countries to audit the competent authority. This list of countries constitutes the so-called “pre-listed” or “pre-harmonized” group. Products imported from those countries may be subject to additional national legislation. Some Member States usually request lists of approved establishments. A list may be fully accepted by one Member State, and partially rejected by another one. It should also be noted that products coming from these countries are allowed to circulate freely in the countries of first entry. If the products concerned have to enter another EU country, the country of first entry shall ask authorization of the remaining 24 EU Member States to allow free circulation of these goods into the Community.

On March 10, the EU has published a new set of Decisions recognizing the U.S. seafood inspection system as equivalent as the European one.

This recognition will facilitate seafood trade between the U.S. and the EU as it removes technical barriers such as 100% controls at border inspection posts and restricted circulation of U.S. seafood products limited to the country of “first port of entry”.

Furthermore, it will create a harmonized framework under which Member States won't have the possibility to impose national requirements on U.S. seafood exporters in addition to EU legislation.

U.S. exporters still need to be approved (either by USDC or the FDA) and registered by the FDA before exporting seafood to the EU.

As of the end of April, US exporters will have to use a new public health certificate, specifically dedicated to American fishery and aquaculture products, for their shipments intended for export to the European Union.

This new status does not apply yet to the export of live bivalve mollusks.

- **Import controls:**

Principles for veterinary checks are laid down in [Council Directive 97/78/EC](#), Council Directive 2002/99/EC and Regulation 854/2004. Inspections of consignments originating from third countries must be carried out on all consignments, at the first point of entry into the E.U. territory and in approved border inspection posts.

Import controls are done in three consecutive steps:

- Documentary check: examination of the health certificate;
- Identity check: visual inspection to confirm consistency between documents and products, verification for the presence of required sanitary marks (country of origin, approval number);
- Physical check: check on the product itself (organoleptic control, packaging, temperature), it may include sampling and laboratory testing.

Products imported from “harmonized” countries, such as the U.S. are subject to the documentary, identity and physical checks at the approved border inspection post at the first point of entry into the E.U. territory. When such a consignment satisfies E.U. requirements, it is then considered as an E.U. product. That is to say that if a consignment can be marketed in one Member State, it can be marketed in all the others without being subject to non-harmonized rules.

If the documentary and the identity checks must be performed on all consignments, the frequency of physical checks is reduced for products from “harmonized” countries from a theoretical 100 per cent to a theoretical 20 percent for fish products in hermetically sealed containers, for fresh and frozen fish, for dry and/or salted products, to 50 percent for other fishery products and for bivalve mollusks.

Each import control (one certificate = one control) is subject to inspection fees.

In the case of processed food containing animal products (surimi for example), the European importer must have an “import license” from the Customs Authorities before the import process occurs.

- **Certification**

Each shipment must be accompanied by a sanitary certificate following the model drawn up by E.U. [Decision 2001/67/EC](#) for fishery and aquaculture products. As of April 24, 2006, a new health certificate, specific to the U.S., will be in force. This new certificate can be found in [Commission Decision 2006/199/EC](#).

In the United States, both the Food and Drug Administration and the US Department of Commerce (National Marine Fisheries Service) have the authority to issue certificates for export to the E.U.

A certificate may be issued for goods produced in different establishments, but can only be made to one consignee. A certificate may be issued for several containers of the same product considered to be a single lot.

In December 2002, the Commission adopted [Council Directive 2002/99/EC](#) “laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption”.

This Directive is in force since January 1, 2005.

The Annex IV of this Directive imposes that the health certificate be issued and signed **before** the bill of lading in all cases. If not, shipments coming from third countries will not be accepted in the EU. Some dispositions of this Directive are still applicable but its Annex IV has been amended by Annex VI of Regulation 854/2004 (see chapter III on food hygiene).

For further information of the concrete implementation of this measure within EU Member States, please contact the European Office of NOAA Fisheries Services.

It must be noted that a certificate defines a lot; therefore a rejection may be decided for all goods covered by the same certificate, even if only a part of it presents a sanitary or documentary problem.

The certificate must be issued in one of the official languages of the country of entry into the E.U. territory, and if necessary in the language of the country of destination. Council Directive 2002/99/EC will authorize, once implemented in the country concerned, the sanitary certificate to be in another language from the one of the country of destination, as long as it is in one of the official languages of the Community. This will be of course at the discretion of the country of destination concerned.

In practice, the veterinary office of the point of entry into the E.U. does the documentary check and issues a Common Veterinary Entry Document (CVED) in conformity with Commission Decision 2003/279/EC (last amended by Commission Regulation 136/2004) which as to be in at least the language or in one of the languages of the border inspection post where the products coming from third countries are introduced into the Community and in the language or in one of the languages of the country of destination of the product. The CVED certificate is described in [Commission Decision 2003/279/EC](#) (applicable since September 1, 2003).

IV- Live Bivalve Mollusks:

A) General Provisions:

[EC Directive 91/492/EEC](#) is the main legislation concerning live bivalve mollusks, tunicates, marine gastropods and echinoderms (named bivalve hereafter). It defines conditions for placing those live animals on the market for immediate consumption. It also set criteria concerning production areas, harvesting and transportation, relaying and purification. In general terms, the

E.U. and the U.S. legislation are very similar when defining several categories of production areas. The main difference remains in the method of control to qualify those areas. The E.U. requests tests to be performed on animal flesh, where the United States relies on water tests. E.U. officials unofficially state that both methods appear to be in good correlation for bivalve mollusks such oysters and mussels. Results differ for clams in general.

B) Imports:

As for fish and fishery products, live and processed bivalve mollusks can be imported only from approved countries. As it is the case for fishery and aquaculture products, two lists exist with “harmonized” and “pre-approved” countries ([Commission Decision 2002/469/EC](#)).

A health certificate that may be obtained from the Food and Drug Administration or the US Department of Commerce (National Marine Fisheries Service) must accompany each consignment. Decision 96/333/EC describes the model certificate to use for the export of live bivalve mollusks. Certificates will be delivered only for products originated from U.S. establishments listed in the FDA Interstate Certified Shellfish Shippers List.

As for fish and fishery products, the certificate must be at least in one of the official languages of the country of entry into the European Union.

Scallops are an exception. Directive 91/492 concerns only farmed scallops. Wild-caught Pectinidae may be imported from any country that is authorized to export fish and fishery products. In this case, they must be partially processed (at least frozen, shelled) and roe-off.

Live and roe-on wild-caught scallops, and all type of farmed scallops must be imported only from countries approved or pre-approved for bivalve mollusks.

Decision 96/333/EC was due to expire on December 31, 2005 (per Decision 2004/119/EC amending it). As a consequence, some EU Member States may be tempted to refuse entry to such shipment of bivalve mollusks from the U.S.

Decision 96/333/EC is still valid.

The new Food Hygiene legislation – in force since January 1, 2006 – implies the continuation of some existing Decisions, including 96/333/EC (Article 4, paragraph 3 of Directive 2004/41/EC).

C) Member States requirements:

For non-harmonized countries, of which the United States is one, E.U. Member States may or may not accept live bivalve mollusks to be imported for immediate human consumption.

Since August 2002, the following Member States have indicated their national requirements:

France:

Live bivalve mollusks must be imported in closed packages that may be sold as such to retailers. The French measure is intended to prohibit the relaying of imported mollusks in their coastal area to avoid development of “exotic” diseases. It is advisable to use packaging of less than 15 kg. The so-called “Re-shippers”, according to FDA definition, cannot be listed in Part II of the certificate, as they are not considered as the establishment of origin.

Italy:

Italian authorities made clear that no live bivalve mollusks would be accepted on the Italian territory unless the European Commission has approved the country of origin (List I).

Spain:

Spain prohibits the imports of live bivalve mollusks from the US. Only frozen and/or processed bivalve mollusks are authorized (Royal Decree 2/2001 of May 24, 2001).

V – Aquaculture products:

In the field of aquaculture, the relevant legislation covers any placing on the market within each individual Member State (MS), the intra-community trade and imports into the European Union. It means that products coming from aquaculture within the EU and from any third country must broadly be equivalent in terms of animal health requirements.

The animal health conditions governing the placing on the market of aquaculture animals and products are defined in [Council Directive 91/67/EC](#).

Since May 1, 2004 new rules are in place for the imports of aquaculture products or animals. These new procedures require that each shipment of aquaculture products be accompanied not only by a public health certificate but also by an animal health certificate.

This new Legislation is covered by the following Regulations:

[Commission Decision 2003/858/EC](#) laying down the animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption; as amended by [Commission Decision 2004/454/EC](#).

[Commission Decision 2003/804/EC](#) laying down the animal health conditions and certification requirements for imports of mollusks, their eggs and gametes, for further growth, fattening, relaying or human consumption; as amended by [Commission Decision 2004/319/EC](#), [Commission Decision 2004/609/EC](#), [Commission Decision 2004/623/EC](#) and [Commission Decision 2005/409/EC](#).

These three last amendments are of particular interest to U.S. exporters.

Commission Decision 2004/609/EC says that the U.S. is authorized to exports mollusks (from aquaculture) not only for human consumption (2004/319/EC) but also for further growth, fattening or relaying.

However, Commission Decision 2005/409/EC reduces the number of U.S. regions from which the export of live mollusks for further growth, fattening, or relaying and for further processing before human consumption.

Commission Decision 2004/623/EC suppresses the need for an animal health attestation – in addition to a public health certificate – for mollusks intended for direct human consumption, under some labeling conditions.

VI- Duties and Trade measures:

A) Background:

All E.U. fish tariffs have been consolidated in the GATT agreement of the Tokyo Round. The overall average of E.U. duties for Chapters 3, 1604 and 1605 is 17.2%, one of the highest in the world. The tariff range goes from 0% (live eels) to 25% (canned mackerel, bonito and anchovies). The main Legislation covering tariffs is [Commission Regulation 1719/2005](#). However, the E.U. provides different mechanisms to reduce duties. It claims that its overall tariff average is then reduced to around 3 to 4%.

- An overall duty-free scheme applies to Africa-Caribbean-Pacific (ACP) countries, signatories of the Lomé Convention, for all seafood products.
- [The Generalized System of Preferences](#) (GSP), which applies to developing countries, covers all seafood products of Chapter 3. Products are classified according to different categories (sensitive, semi-sensitive, sensitive and very sensitive).
- The ANDEAN group, meant to help those countries to combat drugs, enjoys duty-free rate on most of Chapter 3 lines.
- “Access to markets” for “Access to Resources” is the preferred E.U. strategy of fish trade negotiations. Some advantages are so granted, product-by-product, following signatures of fishing agreements (Argentina: reduced duty for hake fillets; Morocco: duty-free imports of canned sardines...)

Recognizing the needs of its processing industry, the E.U. unilaterally reduces duties for certain portions of its imports using two yearly mechanisms, suspensions and autonomous quotas. Most of the products concerned must be further processed within the E.U.

For a better impact, reduced duties must be requested first by the European importer. Suspensions, set on a yearly basis, provide better access for raw material needed by the E.U. industry on an unlimited basis (Alaskan Pollack fillets blocks, hard fish roes). Applied duties may be a full suspension (duty-free) or a reduced duty. Many products are subject to a reference price.

Autonomous quotas ([Council Regulation 379/2004](#)) are opened on a yearly basis (from April 1 until December 31). Each product (or group of products) is subject a quantitative limit. The quota remains opened until the limit is reached. Quantities and reduced duties may change every year depending on Member States’ demands (following national industry requirements) and the compromise reached usually at ministerial level.

Most products are also subject to reference prices. The system of reference prices is based on an essential part of the CFP, the support of fishermen’s incomes. Based on past years landing prices, the E.U. fixes on a yearly basis minimum prices for a wide range of species. Depending on those prices are calculated several aids to Producers Organizations (POs) like withdrawal prices, carry-over aids.

B) Tariff Suspensions:

Council Regulation 1255/96/EC, last amended by [Council Regulation 3000/2006](#), covers tariffs suspensions.

To be entitled to a tariff suspension or reduction, importers must buy the concerned product at a “free-at-frontier” price (C&F) higher than the reference price. Otherwise, products may be imported, but the full conventional rate applies. For example, an autonomous quota is opened for product A with a reduced duty of 5% instead of the conventional 15%, subject to the respect of a reference price of \$100. If the C&F price paid by the importer is:

- \$ 95: the importer cannot access the quota, and must pay a 15% duty;
- \$ 110: the importer can access the quota and will pay a 5% duty.

In October for suspensions, and December for autonomous quotas, the European Commission consults the twenty-five Member States to know about the needs of each national industry. Summing the different needs, a proposal is sent to all governments to be discussed in various committees. A decision has to be made for the December (suspensions) and April (autonomous quotas) Fisheries Councils of Ministers.

It is quite impossible to request a suspension at once for a product not yet entitled to a reduced duty. But a product may be moved from the list of autonomous quotas to the list of suspensions, or quantities of a quota may be increased and its duty further reduced. It is also possible to open new autonomous quotas.

Once a reduced duty has been obtained, the product can be petitioned for a move to a suspension of the tariff. However, the move from reductions to suspension is difficult to obtain.

The EU Fisheries Council of December 1999 adopted the final text for the renewal of the EU Common Organization of Markets for fish and fishery products (2000/104/EC). Some products (surimi, Alaskan Pollock fillets and meat blocks) considered as essential to the EU processing industry to remain competitive will enjoy total or partial suspension of customs duties. For some other products (H&G cod, tuna loins, herring flaps), pluri-annual autonomous quotas at a reduced duty rate have been decided for the period 2004-2006.

Early March 2006, the U.S. and the EU agreed to cut several tariffs for U.S. farm and industrial goods being exported to the ten countries that joined the EU in 2004. This agreement implies a reduction of tariffs on some goods such as chemicals and fish, and an expansion of tariffs quotas for other products like boneless ham, poultry and chocolates.

This change will go into effect no later than July 1, 2006. The ten new Member States were required to change their import tariff regimes when they joined to comply with Brussels’ rules, resulting in some higher tariffs. The U.S. wanted to offset some of these and also asked the EU to expand its quotas to compensate the addition of the ten countries. The fishery products concerned by this agreement are Alaskan Pollock, Hake and Surimi:

The [Compensation Agreement](#) signed between the U.S. and the EU summarizes tariffs reduction for fishery products as follow:

1) 0304 2058 Frozen fillets of Hake

Duty rate of 6.1% instead of 7.5%

2) 0304 2085 Frozen fillets of Alaska Pollock

Duty rate of 14.2% instead of 15%

But tariff suspension (0%) still valid for this product intended for further processing (Council Regulation 104/2000).

3) 0304 9005 Surimi

Duty rate of 14.2% instead of 15%

But tariff reduction to 3.5% still valid for surimi intended for further processing (Reg. 104/2000).

AND autonomous annual quota of 30 000 metric tons at 0% until 12/31/2006 (Regulation 379/2004).

On a more global scale, the U.S. Government is permanently negotiating with the EU a “zero for zero” approach to tariffs in the fisheries sector. Unfortunately, the failure of the Cancun discussions and the slow progress of current negotiations do not predict a rapid agreement on this issue.

For any questions on a specific tariff rate, you may look at the following web site:

http://europa.eu.int/comm/taxation_customs/dds/cgi-bin/tarchap?Lang=EN

VII- Labeling:

A) Legislative Background:

The three main Regulations with respect to labeling are Council Regulation 2000/104/EC, [Council Directive 2000/13/EC](#) (last amended by [Directive 2003/89/EC](#) on ingredients present in foodstuffs) and [Commission Regulation 2065/2001/EC](#). But additional Regulations are expected in the context of “Public safety” and “Organic Food”.

Foot and Mouth disease, BSE crisis, Heavy metals...All these preceding crisis have reinforced the critical need for information, communication and transparency towards consumers.

All new EU Regulation is (and will be) based on consumer confidence and safety in such a way that “the consumer will not be misled by any product or packaging”.

For sanitary purposes, and especially to allow traceability of seafood products, the EU legislation requests that all packages bear the country of origin and the approval number of the establishment of origin. Those two items must be written or printed “indelibly”. The most desirable way would be to have them pre-printed on packages/cartons. In cases where stick-on labels may be used, they must not be easily destructible when attempts are made to remove them, i.e. tear into small pieces. Labels must be in a language “easily understandable” by users. National legislation may ask for the official language(s). It is always better to use that official one. Labels may be in several languages.

Since January 1 2002, [Commission Regulation 2001/2065/EC](#) imposes new requirements for the labeling of fishery and aquaculture products intended to the retail sector. This Regulation only concerns products from Chapter 3 of the Tariff Harmonized System, and not products from Chapter 16 (canned products for instance).

Three sets of information are now compulsory on the label of any fishery and aquaculture products on sales at retailers:

- The Commercial name of the species (the Latin name is not compulsory on the label except if your client requires it). Each Member State has established a list of commercial names applicable. These lists are visible on the EU web site.
- The production method (aquaculture or fishery product). The proper language to use is “caught in...”, “caught in fresh water”, “farmed” or “cultivated”. However Member States may decide whether this information is required when the commercial designation and the area of capture make it obvious that the fish was caught at sea.
- The catch area. Products caught at sea have to show the area of capture (taken from the FAO list, Annex of the above Regulation). However, only the general area has to be mentioned (Pacific ocean for example). The FAO Area code can be mentioned on a voluntary basis. Products caught in fresh water require a reference to the Member State or third country of origin of these products. As for farmed products, the reference is to the Member State or third country in which the product undergoes the final stage of development. Operators may well choose to provide additional information on the area.

To ensure a perfect traceability at all stages of the marketing process, fisheries and aquaculture products have to be accompanied by a document indicating the information described above as well as the Latin name of the products. The document concerned can be the invoice.

Other sets of Regulations regarding ingredients, allergens and guidelines for the implementation of labeling legislation can be download from DG Sanco’s website at:
http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm

B) Concrete labeling examples:

1- Fresh, chilled products:

- Species
 - Country of origin (roman letters, min. 2 cm)
 - Presentation (whole, gutted, fillet, etc)
 - Freshness grade and size category (for species with common standards, min 5 cm)
 - Net weight in kg (except for standard boxes, average net weight is enough)
 - Date of grading and dispatch
 - Name and address (city + state) + “FDA approval #” of processor/packer
- Freshness grading is only for whole/gutted fresh fish.

2- Frozen products:

- Species followed by the word “frozen”
- Country of origin
- Presentation (may be included with the name of the species)
- Net weight in kg
- List of ingredients (except if fish only)
- Date of minimum durability (month/year) or “best before” date.
- Special storage conditions (to be maintained at - 18° C)
- Instructions for use (if not obvious), incl. “do not freeze again once thawed”
- Name and address of the manufacturer, or of a seller in the EC
- “FDA approval #” of the packer (CFN or FEI)
- Lot # (it must begin by “L” or the word “LOT”) (not always mandatory).
- The lot # is defined by the processor in order to be able to trace a product history in case of problem. It can be the production date.

Example: L8110B15 may mean

L = Lot

8 = 1998

110 = day of production

B15 = production line number

3- For deep-frozen foods:

- Freezing date
- Storage conditions and maximum period of storage:

Between 0 and 5 °C : 1 day

***, or between -5 and 0 °C : 1 week

****, or between -12 and -6 °C : 1 month

*****, or at least at -18 °C : up to the best before date.

4- Live bivalve mollusks:

- Species (common name and Latin name)
- Country of dispatch
- Date of wrapping (at least day and month)
- Date of durability or “these animals must be alive when sold”
- Net weight (kg)
- Identification of the dispatch center by its approval number
- Name and address (city + state) of packer + “FDA approval #” (Interstate Certified Shellfish Shipper #)

5- Canned products:

- Name of product
- Country of origin
- Net weight in grams (or liter for liquid products)
- Net drained weight (in case of solid packed in a usually-not-consumed liquid)
- List of ingredients (added water is an ingredient)
- Date of minimum durability (year)
- Any special storage conditions or conditions of use
- Instructions for use (if not obvious)
- Name and address of the manufacturer, or of a seller established within the E.U.
"FDA approval #" of the packer (CFN or FEI)

It is important to note that some Member States as well as countries part of the European Economic Area (EEA) may have additional requirements in terms of labeling of seafood. For further information on labeling, contact our office at the U.S. Mission to the European Union (contact details at the last page of the report).

C) Future labeling legislation

The EU has planned to review its entire food labeling system between 2006 and 2008, with a first set of proposals expected in 2007.

This exercise, aiming at reconciling industry views with consumers' expectations, is predicted to be quite difficult. Consumer groups would like everything to be on the label while the food industry finds EU labeling rules too expensive of a burden.

It is already clear to all operators involved in this process (business operators, consumers, legislators) that the debate will focus on what information should be on a label. What is essential versus what is not? The majority agrees to call for the implementation of the so-called "KISS" principle: Keep It Small and Simple!

On March 10, the Commission (DG Sanco) published a discussion paper entitled "Labeling: Competitiveness, Consumer Information and Better Regulation for the EU". This document is designed to facilitate exchanges between stakeholders but other contributions are welcome.

The consultation paper can be downloaded from DG Sanco's website at:

http://europa.eu.int/comm/food/food/labellingnutrition/betterregulation/competitiveness_consumer_info.pdf

VIII- Other legislation:

Besides the above-mentioned legislation, the E.U. sets various requirements for a wide range of issues. It includes legislation on:

- [Additives](#), colorings, [flavoring](#) and sweeteners allowed within the EU.
- [Traceability of foodstuffs](#).
- [Packaging materials](#): regarding their stability to not transfer substances to foodstuffs in quantities that may be harmful to human health, or change organoleptic properties; regarding waste standardizing information systems for recycling to contribute to environmental protection.
- Wood packing materials: In 2004, the Commission adopted [Commission Directive 2004/102/EC](#) on protective measures against the introduction into the Community of organisms harmful to plants or plants products and against their spread within the Community. On January 17, 2006, the European Union Standing Committee on Plant Health (SCPH) voted to delay until January 1, 2009, the requirement that imported wood packaging material (WPM) be debarked.
The European Commission just published the formal decision ([Decision 2006/14/EC](#)).
As part of its decision to continue to suspend the implementation of the debarking requirement, the SCPH also announced that the matter would be subject to a September 2007 review of the progress made in the International Plant Protection Convention (IPPC) in considering a new international standard which would require debarking. The decision will enable WPM destined for the European Union to continue to be shipped under current European Union regulations which are based on the IPPC internationally agreed upon guidelines for trade in WPM, ISPM15, without any additional markings or declaration that the materials have been debarked. Until this decision, the EU debarking requirement was scheduled to become effective on March 1, 2006."
- Measurement units: the enforcement of E.U. directive on metric labeling only (no imperial measures could be used as dual labeling) is postponed to year 2010.

IX- Points of contact

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